

U.S.S.N. 09/665,303
Filed: September 19, 2000
AMENDMENT AND
RESPONSE TO OFFICE ACTION

Remarks

Applicants thank the Examiner for the helpful interview on June 7, 2005, wherein the undersigned and examiner discussed the active and passive embodiments of applicants' devices and proposed amendments that would emphasize and clarify key distinctions between applicants' devices and the devices disclosed in U.S. Patent No. 5,366,454 to Currie, et al.

Upon entry of the foregoing amendment, 57-110 are pending in the application. In the interest of clarifying the claimed subject matter and reducing the number of independent claims, claims 1-8, 10-16, 18, 19, 21, 23, 24, 26, 43-47, and 49-56 have been canceled and new claims 57-110 have been added. Support for the new claims is found in original claims 1-15, and throughout the specification, including pages 5-11, 23, and 24, and FIGS. 4, 5, 7, 8, and 9. No new matter has been added.

Objection to the Abstract

The Abstract was objected to for including the legal term "comprised" and for having more than 150 words. The objection is respectfully traversed in view of the present amendment to the abstract, which now has less than 150 words and does not include the term "comprised."

Drawings

The drawings were objected to for not including the "packaged" feature recited in claim 1. The objection is respectfully traversed in view of the present amendment to the claims, which no longer include the "packaged" limitation.

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Rejection Under 35 U.S.C. § 102

Claims 1-8, 10-16, 18, 19, 21, 23, 24, 26, 43-47, and 49-56 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,366,454 to Currie et al. (hereinafter “Currie”). The rejection is respectfully traversed as applied to the claims as amended.

Currie discloses a medication-dispensing device that has a plurality of compartments containing doses of medicine. The compartments are sealed with a pre-stressed silicon membrane and have a rupturing system that includes a piezoelectric transducer for applying additional stress to fracture the brittle silicon membrane, so that bodily fluids can enter the compartment and the medicine can be released. A polymeric film is applied over the device to bind broken fragments of the ruptured membrane.

As discussed in the interview, Applicants’ claimed devices utilize release-controlling means that are entirely distinct from those of Currie’s device. First, nothing in Currie discloses or remotely suggests *passive* control means. For example, Currie clearly fails to disclose or suggest a release system comprising drug molecules *dispersed in a matrix material, wherein rate of release of the drug molecules from the reservoir in vivo is controlled by the matrix material*, as required by claims 79-107.

Second, nothing in Currie discloses or remotely suggests control means that utilizes disintegration of *polymeric* or *metal* reservoir caps, or reservoir cap disintegration that is activated by direct application of an *electrical potential through the reservoir cap*, as required by claims 57-78 and 108-110. Because the Currie device relies on a rupturable material that can be fractured by application of a mechanical force (created by deformation of the piezoelectric material) to a pre-stressed thin film having a “predetermined elastic deformation limit and

predetermined rupture point," one of ordinary skill in the art would be *taught away* from replacing the silicon film of Currie with a metal or polymeric material, as these latter materials are relatively elastic and would be unlikely to retain the pre-stressed state required to effectively rupture by the methods taught by Currie. For example, a metal material would tend to creep, or deform under pressure from the constant load of stress-inducing membrane, and thus would not maintain the required "predetermined elastic deformation limit and predetermined rupture point" (See Currie, Col. 5, Lines 49-52; Col, 6, Lines 11-15). Furthermore, nothing in Currie remotely suggests that a reservoir cap disintegration mechanism that involves application of an electrical potential *actually through the reservoir cap itself*. There simply would be no reason to do so in the Currie device, since the Currie mechanism would likely be inoperable that way.

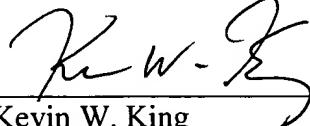
Conclusions

In view of the above amendments and remarks, Applicants respectfully assert that the claims are in condition for allowance. Prompt allowance of each of the pending claims is respectfully solicited.

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The undersigned respectfully invites the Examiner to contact him by telephone (404.853.8068) if any outstanding issues can be resolved by conference or examiner's amendment.

Respectfully submitted,



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